IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Letters Patent of: Rosen et al.

Docket No.: PF596P1N

U.S. Patent No.: 7,601,351

Issued: October 13, 2009

For: ANTIBODIES AGAINST PROTECTIVE ANTIGEN

REQUEST FOR RECONSIDERATION OF DECISION REGARDING PATENT TERM ADJUSTMENT

MS Petitions
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Patentees respectfully request reconsideration of the Decision on Request for Reconsideration of Patent Term Adjustment, mailed April 12, 2010 (the "Decision") regarding U.S. Patent No. 7,601,351 (the "'351 Patent") to the extent that the Decision granted Patentees 1497 days of patent term adjustment ("PTA") rather than the requested 1,542 days of PTA. Patentees maintain that the '351 Patent is entitled to 1,542 days of PTA as set forth in the Request for Reconsideration and in more detail below.

In particular, Patentees disagree with the 45 day reduction of PTA applied by the Office under 37 C.F.R. § 1.703(b)(4), beginning on the date that the Notice of Appeal was filed (October 27, 2008) and ending on the date that the Notice of Allowance was mailed (December 10, 2008) without a corresponding addition of 45 days of PTA pursuant to 35 U.S.C. § 154(b)(1)(C)(iii) and 37 C.F.R. § 1.702(e). Contrary to the Office's position in the Decision and 37 C.F.R. § 1.703(e), Patentees believe that the Examiner's decision to allow the application and issue the patent after Patentees' notice of appeal was "a decision in the review reversing an adverse determination of patentability" pursuant to the statute, and thus the statute requires that Patentees be awarded corresponding "C delay" of 45 days.

This request is being timely made, as it is being submitted within one month of the mail date of the Decision.

STATEMENT OF FACTS

1. The application was filed on June 25, 2003, and is thus eligible for PTA under 35 U.S.C. § 154.

2. The instant application is not subject to a terminal disclaimer.

3. A Notice to File Missing Parts was mailed October 9, 2003. Patentees timely responded on December 9, 2003.

4. Although the instant application was filed on June 25, 2003, the Office failed to initially act on the application within the 14 month permitted time frame allowed under 35 U.S.C. § 154(b)(1)(A)(i). In particular, an office action was not mailed until March 7, 2006. Thus, Patentees are entitled to a PTA of 559 days due to the Patent Office's delay from the day after the date fourteen months after the application was filed (August 26, 2004) to the date of mailing of the first notification under 35 U.S.C. 132 (March 7, 2006). *See* 35 U.S.C. § 154(b)(1)(A)(i) and 37 C.F.R. §§ 1.702(a)(1) & 1.703(a)(1).

5. A complete reply to the March 7, 2006 office action was filed on July 7, 2006 with a petition for an extension of time of three months. Pursuant to 37 C.F.R. § 1.704, this filing incurred a PTA reduction of 30 days from the day after the date three months after the mailing of the office action (June 8, 2006) to the date of the response (July 7, 2006).

6. An Information Disclosure Statement (IDS) was filed on July 11, 2006. According to the PAIR system, a PTA reduction of 4 days was applied as a result of this filing. See PAIR Patent Term Adjustment History (Exhibit A). For the reasons discussed in the PTA Application Under 1.705(b), Patentees do not believe that this PTA reduction is appropriate.

7. A Notice to Comply requesting a new Sequence Listing was mailed on October 13, 2006. For the reasons discussed in the PTA Application Under 1.705(b),

Patentees disagree that this Notice was a proper response under 35 U.S.C. § 132 in compliance with 35 U.S.C. § 154(b)(1)(A)(ii) and 37 C.F.R. §§ 1.702(a)(2) & 1.703(a)(2) to Patentees' July 7, 2006 reply.

8. A response to the Notice to Comply was filed on January 16, 2007, with a petition for an extension of time of two months. Pursuant to 37 C.F.R. § 1.704, this filing incurred a PTA reduction of 3 days from the day after the date three months after the mailing of the Notice (January 14, 2007) to the date of the response (January 16, 2007).

9. A non-final office action responsive to Patentees' July 7, 2006 reply was mailed on July 19, 2007. For the reasons discussed in the PTA Application Under 1.705(b), Patentees believe that the Office failed to respond under 35 U.S.C. § 154(b)(1)(A)(ii) within the 4 month permitted time frame after Patentees' July 7, 2006 reply. Thus, Patentees are entitled to a PTA of 254 days due to the Patent Office's delay from the day after the date four months after date the reply was filed (November 8, 2006) and ending on the date of mailing of the non-final office action under 35 U.S.C. 132 (July 19, 2007). *See* 37 C.F.R. §§ 1.702(a)(2) & 1.703(a)(2).

10. A response to the July 19, 2007 non-final office action was filed on January 22, 2008 with a petition for an extension of time of three months. Pursuant to 37 C.F.R. § 1.704, this filing incurred a PTA reduction of 95 days from the day after the date three months after the mailing of the office action (October 20, 2007) to the date of the response (January 22, 2008).

11. A final office action was mailed on April 28, 2008.

12. A response to the final office action was filed on October 27, 2008 with a petition for an extension of time of three months. Pursuant to 37 C.F.R. § 1.704, this filing incurred a PTA reduction of 91 days from the day after the date three months after the mailing of the office action (July 29, 2008) to the date of the

response (October 27, 2008).

13. On December 10, 2008, a Notice of Allowance was mailed. Together with the Notice of Allowance, a Determination of Patent Term Adjustment (Form PTOL-85) under 35 U.S.C. § 154(b) was mailed indicating a PTA of 400 days.

14. The issue fee transmittal form was filed, and the issue fee was timely paid, on March 6, 2009.

15. The PTA Application Under 1.705(b) was filed on March 6, 2009.

16. The Decision was mailed September 14, 2009, indicating that the PTA Application Under 1.705(b) was dismissed.

17. The '351 Patent was issued on October 13, 2009. Accordingly, the Office failed to issue the '351 Patent within four months of the payment of the issue fee pursuant to 35 U.S.C. § 154(b)(1)(A)(iv). Thus, Patentees are entitled to a PTA of 99 days due to the Patent Office's delay from the day after the date four months after the issue fee was paid (March 7, 2009) to the date of issuance of the '351 Patent (October 13, 2009). *See* 35 U.S.C. § 154(b)(1)(A)(iv) and 37 C.F.R. §§ 1.702(a)(4) & 1.703(a)(6).

18. The Office also failed to issue the '351 Patent within three years of its actual filing date pursuant to 35 U.S.C. § 154(b)(1)(B). Thus, Patentees are entitled to PTA of 1,206 days due to the Patent Office's delay from the day after the date three years after the application was filed (June 26, 2006) to the date that the patent was issued (October 13, 2009), to the extent that such delay does not overlap with other periods of delay. *See* 35 U.S.C. §§ 154(b)(1)(B) and 154(b)(2) and 37 C.F.R. § 1.703(b).

19. Other than the circumstances described above, there have been no circumstances that could reasonably be construed as a failure to engage in reasonable efforts to

conclude processing or examination of this application.

20. On September 30, 2008, the U.S. District Court for the District of Columbia decided *Wyeth v. Dudas*, 580 F. Supp. 2d 138 (D.D.C. 2008). In *Wyeth*, the District Court disagreed with the PTO's interpretation that the entire period during which an application is pending before the PTO (excluding the periods of 35 U.S.C. § 154(b)(1)(B)(i)-(iii)) is the relevant period for determining whether periods of delay under 35 U.S.C. § 154(b)(1)(B) (37 C.F.R. §§ 1.702(b) and 1.703(b)) overlap with periods of delay under 35 U.S.C. § 154(b)(1)(A) (37 C.F.R. §§ 1.702(a) and 1.703(a)). Specifically, the District Court disagreed with the PTO's interpretation because it considers an application as delayed under 35 U.S.C. § 154(b)(1)(B) during the period before it has been delayed under the three-year pendency provision. In addition, the District Court found the language in 35 U.S.C. § 154(b)(2)(A) and 37 C.F.R. § 1.703(f) regarding the overlap of the periods was not ambiguous and indicated that delays under 35 U.S.C. § 154(b)(1)(B) ("B delays" in *Wyeth*) begin "when the PTO has failed to issue a patent within three years, not before." *Wyeth* is controlling authority with respect to the interpretation of 35 U.S.C. § 154(b)(2)(A) by the Office.

21. On November 13, 2009, Patentees filed a Request for Reconsideration of Decision on Application for Patent Term Adjustment under 37 C.F.R § 1.705(b) and Application for Patent Term Adjustment under 37 C.F.R. § 1.705(d), requesting that the patent term for the '351 patent be adjusted to 1,542 days or 1,546 days.

22. On December 11, 2009, Patentees submitted a Request for Certificate of Correction, requesting correction of the typographical errors of the '351 patent.

23. On January 19, 2010, the Office issued a Certificate of Correction, correcting the typographical errors of the '351 patent.

24. On April 9, 2010, Patentees filed a civil action against the Director of the United States Patent Office in the United States District Court for the District of

Columbia, seeking judgment pursuant to 35 U.S.C. § 154(b)(4)(A) that the patent term adjustment for the '351 patent be changed from 983 days to at least 1,542 days.

25. On April 12, 2010, the Office issued a decision on the petition filed November 13, 2009, granting the petition in-part. The period of adjustment was extended from 983 days to 1497 days, reflecting a 45 day reduction in term under 37 C.F.R. §1.703(b(4).

ARGUMENT

Patentees disagree with the Office's 45 day reduction of PTA under 37 C.F.R. § 1.703 (b)(4) beginning on the day of filing of the Notice of Appeal (October 27, 2008) and ending on the day the Notice of Allowance was mailed (December 10, 2008) in the Decision without a corresponding addition of 45 days of PTA pursuant to 35 U.S.C. § 154(b)(1)(C)(iii) and 37 C.F.R. § 1.702(e).

In particular, Patentees believe that a corresponding addition of 45 days of PTA pursuant to 35 U.S.C. § 154(b)(1)(C)(iii) and 37 C.F.R. § 1.702(e) should have been made due to the Examiner's decision to allow the application and issue the patent after Patentees' notice of appeal, as that decision was "a decision in the review reversing an adverse determination of patentability" pursuant to the statute. Nothing in the statue indicates that the decision reversing the adverse determination of patentability must be made by the Board or a Federal court in order for term adjustment to be made under 35 U.S.C. § 154(b)(1)(C)(iii), merely that the decision must be made "in the review." To the extent that 37 C.F.R. § 1.703(e) suggests otherwise, Patentees respectfully assert that rule is inconsistent with the plain meaning of 35 U.S.C. § 154(b)(1)(C)(iii), and reflects an incorrect, and indeed arbitrary, interpretation of the statute by the Office. In the instant case, the Decision's reduction of PTA under 37 C.F.R. § 1.703(b)(4) reflects the Office's acknowledgement that the Examiner's decision came "in the review," and indeed ended that review.

The Office's position that patentees are not entitled to PTA during the period after a notice of appeal was filed in response to an unwarranted final rejection when an Examiner reconsiders and reverses that adverse decision prior to a Board or court decision cannot be

proper. The same decision made later by the Board would certainly permit such PTA, and it would be patently unfair and unjust for a unilateral act by the Office (in the person of the Examiner) in mooting a patentee's appeal by issuing a notice of allowance to yield a different outcome. Indeed, under the Office's interpretation, an Examiner could allow a patent on the eve of a Board decision after years of a pending appeal and strip an patentee of the lengthy PTA accumulated under 35 U.S.C. § 154(b)(1)(C)(iii) without any recourse for the patentee. Nothing in the statute requires such an outcome. Rather, the statute's plain meaning necessitates a conclusion that a decision by the Office to reverse an adverse determination of patentability by allowing an application during the pendency of an appeal, as was done here, requires that appropriate PTA be awarded under 35 U.S.C. § 154(b)(1)(C)(iii).

CONCLUSION

Accordingly, Applicants respectfully request that the PTA for the instant application be reconsidered and corrected to 1,542 days. If any further information is required, please contact the undersigned at the number listed below. Please charge any additional fees due in connection with the filing of this paper, or credit any overpayment, to Deposit Account No. 08-3425.

Dated: May 12, 2010

Respectfully submitted,

/Mark J. Hyman/
Mark J. Hyman
Registration No.: 46,789
HUMAN GENOME SCIENCES, INC.
Intellectual Property Dept.
14200 Shady Grove Road
Rockville, Maryland 20850
(240) 314-1224